REMARKS

Claims 1-12, 23 and 24 are rejected. Claims 1-4, 8 and 23-24 have been cancelled. Claims 5-7 have been amended. Claim 25 is new. Hence claims 5-7 and 25 currently are pending.

Claims 1-8 and 23-24 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In response, claims 1-4, 8 and 23-24 have been cancelled and, thus, the 112 rejections to those claims are considered moot. Further, claim 5 has been amended to correct the informality. Applicants have amended claims 6 and 7 to correct the insufficient antecedent basis per the Examiner's helpful suggestion. Based on the foregoing, all claims are believed to be in compliance with 35 U.S.C. 112.

The Examiner rejected claims 1-8 and 13-24 under 35 U.S.C. 102(a) as being anticipated by Manker et al. (2003/0023238 A1). The Examiner contends that Manker et al. discloses the claimed method for operating a hyperthermia treatment system and a device for performing hyperthermia treatment. The applicant respectfully traverses. However, to further clarify the differences between the cited patent and applicant's invention, claims 5-7 have been amended and new claim 25 has been added.

Applicant has added a new claim 25 which recites a method of non-invasive hyperthermia treatment of a lesion comprising controlling the power output of a radiofrequency energy system to maintain a target temperature, maintaining the target temperature by continuously measuring the difference between the target temperature and the temperature of the lesion, and

terminating a treatment when evaluation of one or more criteria pertaining to a thermal dose being delivered indicates treatment of the lesion. The radiofrequency energy system comprises a radiofrequency radiating source connected to an applicator having a temperature sensor connected to a high-voltage probe, which temperature sensor continuously measures the temperature of the lesion, and a ground probe. The radiofrequency energy system further comprises a processor that determines when the target temperature has been provided, continuously evaluates one or more criteria pertaining to a thermal dose being delivered, and terminates a treatment when evaluation of one or more of the criteria indicates treatment of the lesion.

None of the prior art references, including the Manker et al. reference or US patent 6,612,217 (Kannenberg et al.), teach or suggest the non-invasive hyperthermia treatment of a lesion as set forth in the instant invention. In contrast, Fig. 1 of Manker et al discloses a method for operating a hyperthermia treatment system wherein the sensor is placed internally adjacent to the treatment region via a urethrally-inserted catheter. As Manker et al. teaches at [0033] "[w]hen a heating catheter or non-cooled electromagnetic-radiating catheter is used the highest temperatures are reached **in** the urethra" (emphasis added). Manker et al. teaches a catheter adapted to enclose an energy radiating applicator for radiating energy through the wall of the catheter, along the length of an antennae coiled within the catheter [0037]. Thus, new independent claim 25 is not anticipated by Manker et al. because Manker et al. does not disclose a noninvasive method for treating an external lesion.

Claim 5, as amended, recites a device for performing non-invasive hyperthermia treatment of a lesion, comprising a radiofrequency energy source for providing localized energy for the non-invasive treatment, an applicator connected to the radiofrequency energy source comprising a ground probe and a temperature sensor connected to a high voltage probe for continuously measuring the difference between a target temperature and a temperature of the lesion, and a processor for controlling output of the radiofrequency energy source to maintain a target temperature that determines when the target temperature has been provided, continuously evaluates one or more criteria pertaining to a thermal dose being delivered, and terminates a treatment when evaluation of one or more of the criteria indicates treatment of the lesion.

The Applicants further submit that amended claim 5 is not an obvious variation on Manker et al. Manker et al. teaches an energy radiating applicator enclosed within a catheter. The energy radiating applicator radiates energy through the wall of the catheter to the body tissue surrounding the catheter. In the instant invention, the probes are encased within an applicator housing that is pressed against the lesion, the energy is conducted from one probe through the lesion to the other probe elevating the temperature of only the area between the probes. Because one or more temperature sensors are connected to a high-voltage probe of the present invention the amount of applied energy can be controlled during temperature ramp up and a target temperature can be maintained for a predetermined time, thereby minimizing treatment times. Hence, the Applicants' invention provides an efficient-of-operation advantage that is not recognized (or even possible) in Manker et

al. or any other prior art hyperthermia treatment system, particularly those that involve a catheter system.

The Applicants' present applicator system also provides an unexpected benefit in that by mounting the temperature sensor in the high-voltage probe temperature may be properly sensed even if the ground electrode is not firmly in contact with the lesion. Even if the ground electrode is not firmly in contact with the tissue, there may be some capacitive coupling to the skin, which may allow heating to take place. This heating would not be accurately sensed if the temperature sensor were located in the ground electrode. Moreover, the dual probe system of the instant invention obviates the need for external grounding, thereby eliminating arcing. Consequently, claim 5 is not anticipated. Claims 6 and 7, as amended, are believed to be in allowance as each is dependent from an allowable base claim.

The Office Action rejects claims 9-12 under 35 U.S.C. 103(a) as being unpatentable over Manker et al as being "'typical' performance/calibration test methods" as are well known in the art. The above 103 rejections are considered moot in view of the claims cancelled.

Applicants believe that all information and requirements for the application have been provided to the USPTO. If there are matters that can be discussed by telephone to further the prosecution of the Application, Applicants invite the Examiner to call the undersigned attorney at the Examiner's convenience.

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The Commissioner is hereby authorized to charge any fees due with this Response to U.S. PTO Account No. 17-0055.

Respectfully submitted,
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